

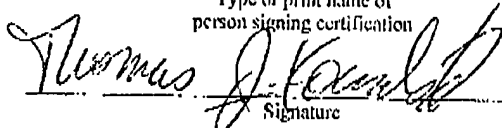
PATENT  
830010-2002.2#17  
MP  
11/18/03**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s) : Pasternak et al.  
Serial No. : 09/975,812  
For : TOPICAL ANESTHETIC/OPIOID  
FORMULATIONS AND USES THEREOF  
Filed : October 11, 2001  
Examiner : M. Bahar  
Art Unit : 1617

745 Fifth Avenue  
New York, NY 10151**FACSIMILE**

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Signature

November 3, 2003

Date of Signature

**DECLARATION OF GAVRIL PASTERNAK UNDER 37 C.F.R. §1.132**

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

I, Gavril Pasternak, hereby declare as follows:

1. I am a citizen of the United States of America and a named inventor in the above-identified application. I respectfully submit that I am qualified to speak and render opinions as to the disclosure in the present application and the state of the art, as I am considered an expert in the field and have familiarity with the present application and its prosecution. I either

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performed, supervised or controlled any experimental work reported in the present application, in the ordinary course of business.

2. In accordance with the experimental protocol carried out in Example 2, the individual dosage forms of morphine and lidocaine administered topically to subjects in combination were:

|        | Morphine Dosage  | Lidocaine Dosage  |
|--------|------------------|-------------------|
| Set #1 | 1.5 mM morphine  | 0.22 mM lidocaine |
|        | 1.5 mM morphine  | 0.45 mM lidocaine |
|        | 1.5 mM morphine  | 0.9 mM lidocaine  |
|        | 1.5 mM morphine  | 1.8 mM lidocaine  |
| Set #2 | 3.0 mM morphine  | 0.45 mM lidocaine |
|        | 3.0 mM morphine  | 0.9 mM lidocaine  |
|        | 3.0 mM morphine  | 1.8 mM lidocaine  |
| Set #3 | 4.5 mM morphine  | 0.22 mM lidocaine |
|        | 4.5 mM morphine  | 0.45 mM lidocaine |
|        | 4.5 mM morphine  | 0.9 mM lidocaine  |
| Set #4 | 0.4 mM morphine  | 0.45 mM lidocaine |
|        | 0.75 mM morphine | 0.45 mM lidocaine |
|        | 1.5 mM morphine  | 0.45 mM lidocaine |
|        | 3.0 mM morphine  | 0.45 mM lidocaine |
|        | 6.0 mM morphine  | 0.45 mM lidocaine |
| Set #5 | 0.75 mM morphine | 0.9 mM lidocaine  |
|        | 1.5 mM morphine  | 0.9 mM lidocaine  |
|        | 3.0 mM morphine  | 0.9 mM lidocaine  |
|        | 4.5 mM morphine  | 0.9 mM lidocaine  |
| Set #6 | 0.75 mM morphine | 1.8 mM lidocaine  |
|        | 1.5 mM morphine  | 1.8 mM lidocaine  |
|        | 3.0 mM morphine  | 1.8 mM lidocaine  |
|        | 4.5 mM morphine  | 1.8 mM lidocaine  |

3. Each set was used to calculate the ED<sub>50</sub> of either morphine or lidocaine at the specified fixed dose of the other.

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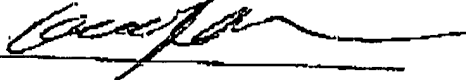
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4. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

11/02/03  
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Gavril Pasternak, M.D., Ph.D.

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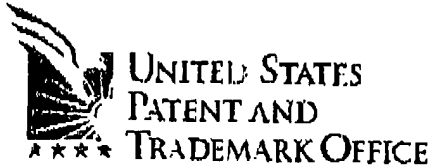
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